Nutter

FACSIMILE TRANSMITTAL SHEET

Today's Date: July 19, 2004 Time: 2:33 PM Employee ID: 9993 # of Pages: 15

From: Thomas J. Engellenner	Direct Dial: 617-439-2948	Fax No: 617-310-9948

RECIPIENT	COMPANY	FAX NO.	PHONE NO.
Director Group Art Unit 1600	USPTO	703 872-9306	

COMMENTS:

Re: Petition to Director to Review Restriction Requirement Pursuant to 37 C.F.R. § 1.144

Please deliver attached Petition to:

Director of Group Art Unit 1600

Certificate of Facsimile Transmission (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being transmitted to the United States Patent and Trademark Office, via facsimile to: Director of Group Art Unit 1600 at *703-872-9306* on the date set forth below.

July 19, 2004	By:
Date of Signature and Transmission	Thomas J. Engellenner Reg. No. 28,711

1346569.1

IF THERE IS A PROBLEM WITH THIS TRANSMISSION, OR IF YOU DID NOT RECEIVE ALL PAGES, PLEASE CALL 617-439-2676, AS SOON AS POSSIBLE

FOR NUTTER McCLENNEN & FISH LLP USE ONLY Client-Matter No. 102729-14

OFFICIAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Kimberly A. Gillis et al. Application No.: 09/996,529 Confirmation No. 3553 Filed: November 28, 2001 For: Expression Analysis of Inhibitor of Differentiation Nucleic Acids and Polypeptides Useful In the Diagnosis and Treatment of Prostate Cancer Attorney Docket No.: 102729-14	Group Art Unit: 1642 Examiner: Davis, Minh Tam B.

Certificate of Facsimile Transmission (37 C.F.R. 1.8(a))

I hereby certify that this correspondence is being transmitted to the United States Patent and Trademark Office, via facsimile to: Director of Group Art Unit 1600 at *703-872-9306* on the date set forth below.

19 July 2004		By:
Date of Signature and Transmission		Thomas J. Engellenner Reg. No. 28,711

Director of Group Art Unit 1600
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO DIRECTOR TO REVIEW RESTRICTION REQUIREMENT

PURSUANT TO 37 C.F.R § 1.144

Dear Sir:

Pursuant to 37 C.F.R § 1.144, Applicants respectfully request that the Director review and reconsider the Restriction Requirement mailed from the Patent Office on February 17, 2004 and made final in the Office Action mailed May 19, 2004.

In the Office Action mailed from the Patent Office on February 17, 2004, the Examiner divided the 35 pending claims into 34 patentably distinct groups requiring election of one of the following 34 groups:

Groups 1-3: Claims 1-7, 11-16; Class 435, subclass 6.
Method detecting prostate cancer by measuring mRNA level or ID1 or ID3 marker or combination

Groups 4-6: Claims 1, 3-10; Class 435, subclass 7.1.
Method of detecting prostate cancer by measuring protein level of ID1 or ID3 marker or combination

Groups 7-9: Claims 17-21; Class 435, subclass 6.
Method of monitoring progression of prostate cancer by measuring mRNA level of ID1 or ID3 marker or combination.

Groups 10-12: Claims 17, 19-21; Class 435, subclass 7.1.
Method of monitoring progression of prostate cancer by measuring protein level of ID1 or ID3 marker or combination.

Groups 13-14: Claims 22, 35; Class 435, subclass 6.
Method of assessing efficacy of treating prostate cancer by measuring mRNA level of ID1 or ID3 marker.

Groups 15-16: Claims 22, 35; Class 435, subclass 7.1.
Method of assessing efficacy of treating prostate cancer by measuring protein level of ID1 or ID3 marker.

Groups 17-18: Claim 23: Class 435, subclass 6.
Method of assessing the potential of a test compound to trigger prostate cancer by measuring mRNA level of ID1 or ID3 marker.

Groups 19-20: Claim 23: Class 435, subclass 7.1.
Method of assessing the potential of a test compound to trigger prostate cancer by measuring protein level of ID1 or ID3 marker.

Groups 21-22: Claim 24: Class 514, subclass 2.
Method for treating prostate cancer by administering ID1 or ID3 protein.

Groups 23-24: Claim 25: Class 514, subclass 44.
Method for treating prostate cancer by expressing ID1 or ID3 protein by an expression vector.

Groups 25-26: Claims 26-27, 29: Class 435, subclass 6.
Method for identifying a compound useful for treating prostate cancer by measuring the mRNA level of ID1 or ID3 markers in the presence or absence of the compound.

Groups 27-28: Claims 26, 28-29: Class 435, subclass 7.1.
Method for identifying a compound useful for treating prostate cancer by measuring the protein level of ID1 or ID3 markers in the presence or absence of the compound.

Groups 29-30: Claims 30-31: Class 435, subclass 7.1.
Method for identifying a compound useful for treating prostate cancer by measuring the activity of ID1 or ID3 markers in the presence or absence of the compound.

Groups 31-32: Claims 32-33: Class 514, subclass 44.
Method for treating prostate cancer comprising administering a compound which increases the mRNA level of ID1 or ID3.

Groups 33-34: Claims 32, 34: Class 514, subclass 44.
Method for treating prostate cancer by administering a compound which increases the protein level of ID1 or ID3.

For the purpose of being responsive to the Restriction Requirement mailed from the Patent Office on February 17, 2004, Applicants elected Group 3, claims 1-7 and 11-16 (drawn to methods of detecting prostate cancer by measuring mRNA level of a combination of the ID1 and ID3 markers) with traverse. However, Applicants respectfully believe that the restriction requirement, as issued, is improper and respectfully request reconsideration.

Applicants' invention is directed to using Inhibitor of Differentiation (ID) markers, *e.g.*, ID-1 and ID-3, as genetic markers for the detection, diagnosis, treatment and prognosis of prostate disorders. The invention provides methods and screening assays for the detection and

diagnosis of prostate cancer, as well as for testing for compounds that effect the expression levels of ID proteins in prostate cancer.

Applicants respectfully request that the Director reconsider the restriction requirement in light of the arguments presented below. Specifically, Applicants request that both markers, ID1 and ID3, of the present invention be examined in this application because examination of *two sequences* does not present an undue burden on the Examiner.

In addition, Applicants believe that the invention should not be restricted to either nucleic acids or proteins since the claims are directed to measuring the expression level of ID markers which can be monitored by *either* measuring the nucleic acids associated with ID (e.g., RNA, or DNA), or the ID protein levels.

Alternatively, if the Director considers nucleic acids and proteins to be separate and distinct inventions, the Applicants respectfully requests that the Director amend the grouping such that all claims directed to either nucleic acids or proteins are examined together.

Examination of Two Sequences Does Not Constitute a Serious Burden

Applicants disagree with the restrictions imposed by the Examiner in that they split up the two markers, ID1 and ID3, of the claimed invention. The screening methods described by the invention encompass *both* markers, individually and in combination. Forcing an election between the two markers, ID1 and ID3, is totally unnecessary. According to MPEP 803.04:

> "the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." (Emphasis added.)

Applicants believe that examining *two sequences* would not present a serious burden to the Examiner since it is only one-fifth of the number determined to be a "reasonable number for examination purposes." Furthermore, Applicants contend that the two sequences, ID1 and ID3, do not fall into the "exceptional" category that would necessitate that the reasonable number of sequences be less than ten. In addition, Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, clarified the PTO's policy for examination of patent applications that claim large numbers of nucleotide sequences in his Notice entitled "Examination of Patent Applications Containing Nucleotide Sequences" (October 17, 1996, 1192 OG 68). The Notice elaborated on the PTO's policy of *not* restricting combination of nucleotide sequences:

> "Applications claiming only a combination of nucleotide sequences ... will generally ***not*** be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable." (Emphasis added.)

Applicants also stress the PTO's statement that allowing Applicants to claim more than one "independent and distinct nucleotide sequences in a single application will promote efficient, cost-effective examination" See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996). Thus, Applicants urge that the groups be amended such that the both markers ID1 and ID3 are examined in this application.

Nucleic Acids And Proteins Encoded Thereby are Not Distinct Inventions

Reconsideration of the restriction requirement is also requested because nucleic acids *encoding for* the ID markers and the ID marker proteins *encoded by* the nucleic acids are not distinct inventions since the nucleic acids and proteins claimed are integrally related. The invention is drawn to measuring the expression levels of ID proteins (e.g., ID1 and/or ID3) associated with prostate cancer. The expression level can be monitored by *either* measuring the nucleic acids associated with ID (e.g., RNA, or DNA), or the ID protein levels. Forcing an election between nucleic acids and proteins would require that the Applicants amend the claims

so that they fit into the groups, as requested by the Examiner in the first Office Action of the merits mailed May 19, 2004. Accordingly, the Director is requested to amend the restriction requirement such that both mRNA and protein of the ID1 and ID3 are examined together in this application.

If the restriction is amended such that nucleic acids and proteins are examined together, Applicants feel that the grouping below would represent a more appropriate restriction:

Proposed Group A: Claims 1-22, 35; Claims directed to assessing prostate cancer using ID markers;

Proposed Group B: Claims 23-31; Claims directed to screening prostate cancer drugs using ID markers; and

Proposed Group C: Claims 32-34; Claims directed to treating prostate cancer with ID markers;

If Nucleic Acids And Proteins are Distinct Inventions, The Restriction Should Group All Nucleic Acids Claims Together and All Protein Claims Together.

The Examiner has taken a position that methods and reagents required to detect proteins are different from those required to detect nucleic acids. Applicants believe that this grouping is improper since the nucleic acids encoding for specific proteins and the proteins that are encoded are integrally related inventions. However, Applicants respond to this improper grouping by stating that if the Director believes that nucleic acids and proteins are separate and distinct inventions, a more appropriate grouping should be based on methods for detecting nucleic acids and on methods for detecting proteins. With this in mind, a more appropriate grouping should be:

Proposed Group I: Claims directed to measuring or using ID *proteins*
Claims 1, 3-10, 17, 19-21, 22-26, 28, 29, 32, 34, and 35

Proposed Group II: Claims directed to measuring or using ID *nucleic acids*
Claims 1-7, 11-16, 17-23, 25-27, 29, 32, 33, and 35

Grouping the inventions into groups directed to either nucleic acids or proteins is a more appropriate grouping. For example, the methods and reagents required to detect the expression of ID nucleic acids to assess whether a subject is afflicted with prostate cancer (claims 1-7, 11-16, 17-22, and 35), are the *same methods and reagents* required to screen prostate cancer drugs (claims 23, 25-27, 29), and to assess treatment of prostate cancer (claims 32, 33). Thus, it would not be a serious burden on the Examiner to search all of the claims relating to ID nucleic acids or relating to ID proteins together. Since the same methods and reagents are used to detect the expression levels of nucleic acids, all claims directed to detecting expression levels of nucleic acids should be examined together. Similarly, since the same methods of reagents are used to detect the expression levels of proteins, claims directed to detecting the expression levels of proteins should be examined together.

CONCLUSION

The Director is urged to reconsider the restriction requirement in light of the above remarks. Specifically, Applicants request that both markers, ID1 and ID3, of the present invention be examined in this application. In addition, Applicants believe that the invention should not be restricted to either nucleic acids or proteins. However, if the Director considers nucleic acids and proteins to be separate and distinct inventions, the Applicants respectfully requests that the Director consider amending the grouping such that all claims directed to either nucleic acids or proteins are examined together. Applicants respectfully request that the Director call the undersigned at the telephone number indicated below so that any remaining issues can be discussed.

This petition is being filed within two months of receiving the first Office Action on the merits. Accordingly, Applicant believes that no fee or certification is required. However, the Director is hereby authorized to charge payment of any additional fees associated with this communication to Deposit Account No. 141449.

Respectfully submitted,
NUTTER, McCLENNEN & FISH, LLP

Date: July 19, 2004

Thomas J. Engellenner
Reg. No. 28,711
Attorney for Applicants
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
Tel: (617)439-2948
Fax: (617)310-9948